REMARKS

In the present Amendment, claim 17 has been amended to replace "to allow the compartments to communicate with one another" with --to allow contents in the compartments to come into contact with one another by opening the partition--. This amendment is supported by the specification, for example, page 26, lines 16-18.

Claims 1-5, 8, 12 and 16-21 have been amended to improve their form and/or clarity. These amendments are not to be deemed to narrow the scope of the claims.

Claims 6, 10, 14, 22, 26, 30 and 34 were previously canceled.

No new matter has been added and entry of the Amendment is respectfully requested. Upon entry of the Amendment, claims 1-5, 7-9, 11-13, 15-21, 23-25, 27-29 and 31-33 will be all the claims pending in the application.

I. Status of Claims

In the Office Action Summary, it is indicated that claims 1-34 are pending.

Applicants submit that claims 6, 10, 14, 22, 26, 30 and 34 were previously canceled in the Preliminary Amendment filed June 3, 2005. Therefore, claims 1-5, 7-9, 11-13, 15-21, 23-25, 27-29 and 31-33 are all the claims pending in the application.

II. Response to Rejection Under 35 U.S.C. § 112, Second Paragraph

Claim 17 is rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Specifically, it is asserted that the meaning of the term "communicate" is unclear.

In response, claim 17 has been amended to recite "to allow contents in the compartments to come into contact with one another by opening the partition" to improve its clarity. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection.

III. Response to Rejection Under 35 U.S.C. § 102

Claims 1-4, 13, 15, 16, 18-20, 29, 31 and 32 are rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Yamada et al (JP 2002-179562A) ("JP '562"), as evidenced by PDRHealth.

Applicants respectfully submit that the present claims are novel and patentable over Yamada et al for at least the following reasons.

JP '562 discloses in claim 1, "[a] stable painless propofol fat emulsion for intravenous injection comprising an O/W-type emulsion containing propofol and lidocaine in an effective amount for relieving pain, the emulsion being adjusted to a pH of 3.0 to 6.5 in the presence of a hydrophilic surfactant of 10 or more HLB contained in the aqueous phase as a stabilizer." That is, the fat emulsion of JP '562 contains propofol and a hydrophilic surfactant of 10 or more HLB as a stabilizer.

On the other hand, present independent claim 1 relates to a fat emulsion with which a local anaesthetic is mixed before use. The fat emulsion comprises propofol, an oily component and an emulsifier, and further comprises one of components (a) to (d) as a stabilizer in a specific amount. Further, present independent claim 18 relates to a pain-relieving fat emulsion

comprising one of the stabilizers (a) to (d) as in claim 1, further contains a local anesthetic. The stabilizers recited in the present claims are completely different from the hydrophilic surfactant of 10 or more HLB described in JP '562.

In addition, the Examiner relies on paragraph [0017] of JP '562 as teaching a fat emulsion preparation comprising lidocaine, propofol, soybean oils and yolk lecithin. The Examiner considers yolk lecithin as a stabilizer. Further, PDRHealth is relied upon as teaching that yolk lecithin is a phosphatidylcholine composed of saturated fatty acids, such as palmitic, stearic, lecithin, oleic acid, and linoleic acids.

Applicants respectfully disagree. As clearly shown in the formula of PDRHealth, phosphatidylcholine is not the same as phosphatidylglycerol, phosphatidic acid, phosphatidylinositol, phosphatidylserine, or phosphatidylethanolamine. Therefore, yolk lecithin is different from components (a) and (b) of the present invention. Furthermore, phosphatidylcholine is not a free fatty acid, and thus is also different from the unsaturated fatty acids (c) of the present invention. That is, yolk lecithin is different from the stabilizers recited in the present claims.

In view of the above, Applicants respectfully submit that JP '562 does not disclose or anticipate the present invention.

Moreover, the present invention provides unexpectedly superior results, which further support the patentability of the present invention. Specifically, as described in the present specification, Comparative Example 1 was prepared in the same manner as Example 9, except that distearoylphosphatidylcholine was used in place of the distearoylphophatidic acid as a

stabilizer. Example 19 described a fat emulsion prepared by mixing lidocaine hydrochloride and the fat emulsifier of Example 9, while Comparative Example 2 described a fat emulsion prepared by mixing lidocaine hydrochloride and the fat emulsion of Comparative Example 1. The stability test results show that the fat emulsion sample of Example 19 containing distearoylphosphatidic acid, in accordance with the present invention, did not separate into two phases twenty-four hours after the addition of lidocaine hydrochloride and exhibited very good emulsion stability. In contrast, the fat emulsion sample of Comparative Example 2 containing distearoylphophatidyicholine, i.e. a choline derivative of distearoylphosphatidic acid, separated into two phases and exhibited poor emulsion stability (Table 5).

As clearly demonstrated from these results, the present invention which requires one of specific stabilizers (a) to (d), provides a fat emulsion having emulsion stability that is not impaired when a local anaesthetic such as lidocaine and/or the like is admixed.

Claims 2-4, 13, 15, 16, 19, 20, 29, 31 and 32 are distinguishable from JP '562 at least by virtue of their dependency.

In view of the foregoing, Applicants respectfully submit that the present claims are not anticipated or rendered obvious by JP '562, and thus the rejection should be withdrawn.

IV. Response to Rejections Under 35 U.S.C. § 103

a. Claims 5, 7-9, 11, 12, 21, 23-25, 27, 28 and 33 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP '562, as evidenced by PDRHealth, and further in view of Unger et al (USP 6,090,800).

Applicants respectfully submit that the present claims are patentable over the cited references for at least the following reasons.

Unger et al. discloses use of a wide variety of lipids as stabilizers for pharmaceutical compositions. The Examiner notes that the examples of lipids include distearoylphophatidylglycerol, palmitic acid, stearic acid, oleic acid, dioleylphosphatidylethanolamine, distearoylphosphatidylethanolamine-polyethylene glycol 5000, and the like.

However, Unger et al. discloses an extremely wide range of compounds as stabilizers in addition to those identified by the Examiner. Unger et al. does not provide any guidance or advantages in selecting those specific stabilizers among the numerous stabilizers exemplified in Unger et al. Further, Unger at al. does not disclose a specific fat emulsion comprising propofol, an oily component, and an emulsifier, as a pharmaceutical composition in which the stabilizers are effectively used. Therefore, Applicants submit that there is no reasonable expectation that the stabilizers described in Unger et al. would provide sufficient emulsion stability in a specific fat emulsion comprising propofol, an oily component, and an emulsifier, when a local anesthetic is admixed.

Moreover, as mentioned above, JP '562 discloses a fat emulsion comprising an O/W-type emulsion containing propofol and lidocaine; it merely discloses a hydrophilic surfactant of 10 or more HLB as a stabilizer. Table 1 of JP '562 presenting the stability test results of some stabilizers does not include stabilizers (a) to (d) used in the present invention, which are completely different from the hydrophilic surfactants of 10 or more HLB, or any compounds

analogous thereto. Accordingly, Applicants submit that it would not have been obvious to one of ordinary skill in the art to substitute the stabilizer of Unger et al. for that in the composition of JP '562.

Additionally, as the Examiner notes, JP '562 discloses a phospholipid content range of 0.5 to 5 wt%. However, JP '562 describes in paragraph [0014], that yolk lecithin and like phospholipids are used as emulsifiers and not stabilizers. Moreover, as described above, yolk lecithin is clearly different from the stabilizers (a) to (d) used in the present invention. Therefore, JP '562 merely discloses the amount of emulsifier ranging from 0.5 to 5 wt%, and not the amount of stabilizer contained in the composition.

In view of the forgoing, Applicants respectfully submit that the present claims are not obvious over the cited references and thus the rejection should be withdrawn.

b. Claim 17 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP '562 and further in view of Yugai (US 2001/0047162).

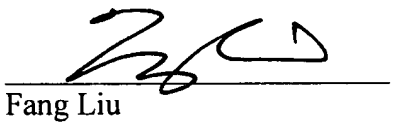
Applicants respectfully submit that present claim 17 is patentable over the cited references for the same reasons as set forth above in Section III.a. In addition, Yugai is relied upon merely as teaching a container having a similar structure to this claimed container, and thus does not rectify the deficiencies of JP '562. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the rejection.

V. Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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